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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,681	12/23/1999	ERIC J. MATHUR	09010/044001	3238

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EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/202,681	MATHUR ET AL.	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-21 and 31-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,2 and 48-52* is/are allowed.

6)☒ Claim(s) *3-5-21 and 31-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment of claims 3-6, 8-11, 18, 19, 21, and the addition of new 45-52 in the paper of 5/18/2004, is acknowledged. Claims 1-11, 13-21 and 31-52 are present for examination.

Applicants' arguments filed on 5/18/2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-17, 20, 21, and 41-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to previous claims 15-17, 20, 21, and 41-43. In response to this rejection applicants have amended claim 21, and traverse the rejection as it applies to the newly amended claims.

Applicants submit that that the claimed invention is fully described in the specification such that one of ordinary skill in the art would recognize that applicants were in possession of the claimed invention at the time of filing and that the description of a genus of polynucleotides in terms of the physico-chemical properties (i.e. a % sequence identity) and function (i.e. encoding a polypeptide having phosphatase activity) satisfies the description requirement. While such a description of a genus of polynucleotides in terms of the physico-chemical properties (i.e. a % sequence identity) and function (i.e. encoding a polypeptide having phosphatase activity) does satisfies the description requirement, applicants have not made such a description of the claimed genus of polynucleotides.

Applicants further submit a Rule 132 declaration by co-inventor Dr. Jay Short to address the Patent Office's concerns regarding the above rejection.

It is noted that the declaration by Dr. Jay Short while it has been considered as a courtesy to applicants, has not been signed by Dr. Short.

The declaration submitted by Dr. Short is fully acknowledged. In this declaration, Dr. Short declares that assays for identifying nucleic acids that encode polypeptides such as phosphatases and that procedures for identifying polypeptides having phosphatase activity under varying conditions were conventional and routine in the art at the time of the invention. Applicants thus submit that accordingly one of ordinary skill in the art using the teaching of the specification would have been able to ascertain what phosphatase-encoding nucleic acids were within the scope of the claims with reasonable clarity to recognize applicants were in possession of the invention at the time of filing.

Applicants further submit that both the Patent Office and the Federal Circuit set forth conditions where a single species is sufficient to put one of skill in the art in possession of the attributes and features of all species within a genus, where the genus is defined in terms of shared physical and structural properties with the single species. Applicants support their submission by referring to the USPTO guidelines concerning compliance with the written description requirement and specifically refer to Example 14 of the guidelines, in which a claim reciting variants by sequence identity to a sequence is sought. Applicants argument is acknowledged, however unlike the referred to example, applicants are claiming that genus that has the referred to structural identity to a minor portion (i.e. 15 nucleotides) of the referred to polynucloetide (that of claim 1). Applicants argument that the claimed species must have a percent identity to an exemplary sequence is acknowledged, however applicants "exemplary sequence" is minor, such that it does not result in a sufficient structural description of the claimed genus. Further, as discussed, this minor structural feature is in sufficient to describe the claimed genus relative to applicants reference to University of California v. Eli Lilly & Co., 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 3, 4, 5, 10, 11, 13-21 and 31-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides which

encode the amino acid sequence of SEQ ID NO: 28 or enzymatically active fragments thereof, does not reasonably provide enablement for those polynucleotides which merely comprise a sequence that hybridizes under the specified stringent conditions to a polynucleotide that encodes the amino acids of SEQ ID NO: 28 or to a polypeptide having phosphatase activity and having merely 70% identity to the sequence of SEQ ID NO: 28, or a complement thereof.

The rejection was stated in the previous office action as it applied to previous claims 3, 4, 5, 10, 11, 13-21 and 31-44. In response to this rejection applicants have amended claims 3-6, 8-11, 18, 19, 21, and traverse the rejection as it applies to the newly amended claims. Claims 45-47 are included in the rejection for the same reasons that the claims from which they depend remain in the rejection.

Applicants traverse this rejection on the basis that methods for changing or varying nucleic acids sequences were well known in the art at the time of invention and that there is no requirement that every way of carrying out an invention be expressly described. The filing of the declaration by Dr. Jay Short in support of applicants position is acknowledged, however, is not found persuasive.

To address this rejection, applicants submit for consideration a Rule 132 expert declaration by Dr. Jay Short. The declaration submitted by Dr. Short is fully acknowledged. In this declaration, Dr. Short declares that procedures for modifying nucleic acids were conventional and routine in the art at the time of invention and that one of ordinary skill in the art using the teachings of the specification would have been able to select any known method of modifying nucleic acids to make a variant of SEQ ID NO: 19 or a variant of a nucleic acid having 70% sequence identity to SEQ ID NO: 19 or a variant of a nucleic acid comprising a fragment of at least 30 consecutive nucleotides of a sequence having at least 70% identity to the sequence set forth in SEQ ID NO: 19, to practice the methods of the invention without undue experimentation.

Applicants argument is not found persuasive because while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan, producing variants as claimed by applicants requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants which are to be modified by the claimed method, have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While applicants continue to argue that the art teaches and is enabled for numerous methods of modification of nucleic acids, the basis for the rejection is not based on the lack of enablement of the different recited nucleic acid modification methods, but rather the lack of enablement of those starting materials of the claimed methods, specifically those nucleic acids having a mere 70% identity to the sequence set for the in SEQ ID NO: 19 or at least 15 consecutive nucleotides of said sequence.

While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As stated previously, the specification does not support the broad scope of the claims which encompass all modifications and fragments of any polynucleotide with the defined structural limitations, because the specification does not establish: (A) regions of the polynucleotide structure which may be modified without its functional activity; (B) the general tolerance of the claimed polynucleotides to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleic acid residue of the polynucleotide with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Applicants declaration stating that it was considered routine by one skilled in the art at the time of the invention to screen for multiple substitutions or multiple modifications in a nucleic acid sequence for functional variations is acknowledged, however, as stated above, while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc, are well known to the skilled artisan, producing variants as claimed by applicants (i.e. encoding a phosphatase) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants produced by as well as used by the claimed method, have the claimed property. Without such guidance one

of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the claimed polynucleotides comprising mere fragments of that polynucleotide which encodes SEQ ID NO: 28. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

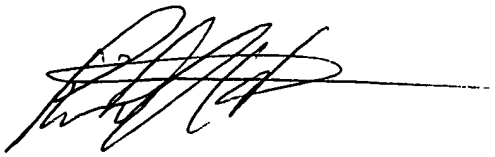
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
7/26/2004